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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/721,774	11/26/2003	Christer Nordstedt	50291/016003	6338

21559 7590 02/15/2006

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EXAMINER	
BORIN, MICHAEL L	

ART UNIT	PAPER NUMBER
1631	

DATE MAILED: 02/15/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/721,774	NORDSTEDT ET AL.	
	Examiner	Art Unit	
	Michael Borin	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 November 0205*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *12-18 and 27-33* is/are pending in the application.

4a) Of the above claim(s) *12,16,27,29,31 and 32* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *13-15,17,18,30,33* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☒ Certified copies of the priority documents have been received in Application No. 09/095,106.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *2 IDS s*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of Claims

Claims 12-18,27-33 are pending

Amendment and response to restriction requirement filed 11/10/2005 is acknowledged. Applicant elected, with traverse, Group IV, claims 12-18,30,33. With respect to claims 27,29,31, inhibition of polymerization of amyloid β peptide is not equivalent to treatment particular diseases which have variable mechanisms of development and etiology. In particular, in regard to treatment of amyloidosis (claim 39), there are several types of amyloidosis (three major types and several less common forms) having different origin[1]. With respect to claim 32, the claim is drawn not to polymerization of β peptide itself, but polymerization of β peptide to a ligand. The restriction requirement is still deemed proper and is therefore made FINAL. Claims 27,29,31,32 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected groups. Cancellation of claims 27,29,31,32 is requested.

With respect to election of species, applicant elected compounds comprising sequence KLVFF. The election is made for examination purposes. Examination of non-elected species will be proceeded to once the claims drawn to the method of use of

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[1]type A is related to variable region of an immunoglobulin light chain, and occurs in primary amyloidosis and in amyloidosis associated with multiple myeloma; the second type has a unique N-terminal sequence of a nonimmunoglobulin protein called AA protein and occurs in patients with secondary amyloidosis; the third type, which is associated with familial amyloid polyneuropathy, is usually a transthyretin (prealbumin) molecule that has a single amino acid substitution. Other hereditary amyloids have been found to consist of mutant gelsolin in some families, mutant apolipoprotein A-I in several others, and other mutant proteins in hereditary cerebralartery amyloid. The amyloid found in the histopathologic lesions of Alzheimer's disease consists of β proteins.

the elected species is deemed allowable. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. Claims 12,16 are withdrawn from consideration. Claims 13-15,17,18,30,33 are addressed to the extent they read on the elected species.

Information Disclosure Statement

Applicants' Information Disclosure Statements filed 11/26/2003 and 11/10/2005 have been received and entered into the application. Accordingly, as reflected by the attached completed copies of forms PTO-1449, the cited references have been considered.

Claim Rejections - 35 USC § 102.

Claims 13-15,17,18,30,33 are rejected under 35 U.S.C. 102(e) as clearly anticipated by Findeis et al. (US 5,854,204).

Findeis describes agents which inhibit β-amyloid peptide aggregation. In particular, establishing the five amino acid subregion of Aβ peptide sufficient for inhibitory activity of a β-modulator compound, the reference specifically points at Aβ 16-20 region, which is KLVFF moiety. See Example 9, cols. 56-57. Particular examples of peptides with KLVFF moiety having inhibitory activity on β-amyloid peptide aggregation

(as reflected by changes in lag time, and/or reduction in turbidity, and/or inhibition in extension assay) are shown in Table V (cols. 61-62). See compounds PPI-319,PPI 348-350, PPI 369-372, PPI 373-375. Further, see col. 18, line 54 through col. 19, line11.

With respect to claim 18, the compounds in Table V have free COOH group which corresponds to R2=H radical of the instant invention.

Further, with respect to claim 17, the modifying group in the modulators of β-amyloid peptide aggregation can be acetyl. See col. 24, lines 19,20.

Further with respect to *in vivo* effects of the modulator compounds (i.e., with respect to claims 13-15,17,18,30), the reference teaches that β-amyloid peptide can be contacted either *in vitro* or *in vivo*, and the latter is delivery of the agent to *in* vivo site where natural β-amyloid peptide is present. The reference teaches that the inhibitors of natural β-amyloid peptide can be used in treatment of disorders associated with β-amyloidosis. See col. 32, first full paragraph, col. 34.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Borin whose telephone number is (571) 272-0713. The examiner can normally be reached on 9am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, Ph.D., can be reached on (571) 272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Michael Borin, Ph.D.
Primary Examiner
Art Unit 1631